HFV-121

FINDING OF NO SIGNIFICANT IMPACT

for

HYDROPHOBIC SILICA

AS A

GRAS SUBSTANCE

G 2419 A0000

DEGUSSA CORPORATION
RIDGEFIELD PARK, NJ

The Center for Veterinary Medicine has carefully considered the potential environmental effect of this action and has concluded that this action will not have a significant impact on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

Degussa Corporation, Ridgefield Park, NJ is requesting approval of their petition for affirmation of the generally recognized as safe (GRAS) status of hydrophobic silica. The product is known by the trade names Aerosil® R 972, a fumed hydrophobic silica, Sipernat D 17, a precipitated hydrophobic silica, and synthetic amorphous hydrophobic silica. The submission proposes to use hydrophobic silica as an anticacking/free-flow agent in vitamin preparations for animal feed. In support of the request, the submission contains an environmental assessment (EA, dated December 23, 1994) formatted according to 21 CFR 25.31a(b)(5) as required for GRAS affirmation petition.

December 23, 1994, EA contains a brief description of the preparation of hydrophobic silica by methylation of the surface of particles of fumed or precipitated amorphous silica. The hydrophobic silica will be manufactured by Degussa Corporation at its manufacturing facilities in Wesseling, and Rheinfelden, Germany. The EA contains letters from Degussa officials certifying that hydrophobic silica production facilities located in Wesseling and Rheinfelden, Germany are operated in compliance with 1) German emission protection laws and regulations 2) German water control laws and its regulations 3) German waste treatment laws and regulations, and 4) provisions for German Trade and Industry. The waste water from the manufacturing facility is neutralized and combined with the wastewater from other silica plant operations. The wastewater is released directly into the Rhine river in compliance with local laws and regulations. The only emission into the air is water vapor and air generated during the drying of hydrophobic silica by direct heating with natural gas. The air flow is filtered to remove dust to confirm to the local emissions regulation.

The EA states that unmodified silica has been safely used as a component of vitamin preparations for animal feed for many years. The silica in unmodified or hydrophobic form is expected to pass through the animal following ingestion and to be excreted unchanged. Due to the inertness of these materials, they are expected to remain unchanged in the environment and not to undergo chemical change or degradation. The EA states that the use of hydrophobic silica in place of silica is not expected to have any effect on the fate and effects of the substance in the environment due to similarities between the two materials.

silica will not be absorbed by the gastrointestinal tract and will be excreted. Hydrophobic silica is stable and expected to degrade very slowly. Approximately 5 million tons of hydrophobic silicas are used commercially in the United States for various purposes. Estimated maximum yearly US market volume for hydrophobic silica for use in vitamin preparations for animal feed will be 6 million pounds or less than 0.1% of the total commercial use in the US. Only small quantities of hydrophobic silica are expected to be released into the environment, either as accidental releases or as a component at low concentrations (< 5 ppm) in animal feces. Due to the insolubility and extremely inert nature of hydrophobic silica, it is unlikely that the anticipated level of release could have any significant adverse environmental effects.

The submission contains relevant toxicological data that supports the safety of hydrophobic silicas to animals and humans. The submitted information indicates that hydrophobic silica and similar silicates are nontoxic at current levels used in food, and the lack of nontoxicity is related to their non absorbability. The submitted data indicate that inherent safety of silicon dioxide, which is ubiquitous in the environment, is not altered by the minor surface alteration involved in producing hydrophobic silica.

The information provided in the submission and in the December 23, 1994, EA indicates that the manufacture and use of the product as a GRAS substance will not have significant impact on the environment.

7/14/95 D M. Jayamanna
Date Preparer, Environmental Safety Branch, HFV-152

7/14/95 [signature]
Date Primary Action Officer, HFV-226

7/14/95 for Roger A. Jones
Date Chief, Environmental Safety Branch, HFV-152

Attachment: Environmental Assessment; dated December 23, 1994